

**SUBSTITUTE SPECIFICATION**

**SHOWING MARK-UPS**

PROCESS FOR THE PRODUCTION OF INTERCHANGEABLE  
VACUUM TEST TUBE HOLDERS FOR TAKING BLOOD  
SAMPLES AND PRODUCT OBTAINED THEREFROM

**DESCRIPTION**

**BACKGROUND OF THE INVENTION**

**[0001] 1. Field of the Invention**

[0002] This patent The present invention concerns devices a device for taking blood samples, and, in particular it concerns the holders more particularly, a holder provided with a needle, for veins or arteries, in into which holder the vacuum test tubes for taking blood samples are inserted, and the process for their the production thereof.

**[0003] 2. Description of Related Art**

[0004] Many Numerous medical diagnoses require the analysis of blood samples which are taken directly from the a patient's vein.

[0005] When blood samples are taken, it is very important to prevent the transmission, both between patients and between patient and nurse, of any diseases, germs, viruses and similar.

[0006] Further, the The nurse must not insert the needle through the vein, penetrating it the vein from side to side, because this produces a haematoma would produce a hematoma in the patient and also because it makes that would make it impossible to take the blood sample.

[0007] The syringe, as a means of taking blood samples from the a patient, has been may be replaced by with a holder provided with a needle, integral with it such holder, and with various vacuum test tubes that are inserted in said into the holder each time.

[0008] The holder consists of a plastic cylinder with the rear end open, and with the front end closed by a circular wall through which the needle passes penetrated by the needle.

[0009] Said cylinder, which is suited to contain ~~the-a~~ vacuum test tube, has the disadvantage of being very wide.

[00010] ~~Part~~ The portion of the needle outside ~~extending out of~~ the holder is inserted in the vein from which the blood sample is to be taken, while the opposite tip of the needle, which is housed inside the holder, pierces the seal cap of the vacuum test tube inserted in the holder, thus conveying the blood inside said vacuum test tube.

[0010] The holders with a needle with two opposite tips that are currently known have the needle positioned centrally, or coaxially, with respect to the holder.

[0011] During the taking of a ~~blood sample~~ sample, when the needle ~~of extending from~~ the holder is inserted ~~in~~ into the patient's vein, the needle penetrates the skin at a very wide angle, ~~as~~ because the thickness of the holder makes it impossible to position the needle near the skin in a substantially tangential position. The nurse is therefore ~~obliged~~ forced to contrive various solutions, such as raising the patient's skin or pressing the holder hard against the patient's skin. All of this does not prevent possible perforation of the vein, however. Furthermore, said contrivances cause discomfort and in some cases even pain to the patient.

[0012] Since the tip of the needle is slanted or lance-shaped, for better insertion ~~in~~ into the skin and ~~in the~~ into a vein, each time the nurse must check the position of the tip of the needle, which must have its oblique side facing upwards for correct insertion into the skin and vein.

[0013] Some nurses use butterfly needles, i.e. small needles provided at the sides with two flat flexible grips and provided with a connection tube ~~for the support or for the connected to a~~ blood container or to a syringe. These butterfly needles simplify insertion into the vein and make the blood sampling less painful, but at the same time the nurse ~~has to~~ must prepare the butterfly needle, connect it to the support ~~container~~ or syringe, insert the butterfly needle into the vein and keep it in position with her/his hand or ~~a~~ plaster ~~an adhesive bandage~~ throughout the sampling operation. Furthermore, butterfly needles are expensive to purchase and dispose of.

[0014] Holders exist that are provided with a non-central needle, i.e. a needle positioned near the side wall of the holder and parallel to it. These holders are described in the patent US Patent 5938622.

[0015] Although these holders theoretically ~~permit~~ enable a better insertion of the needle into the vein, they are expensive and difficult to produce. ~~These~~ ~~The related~~ vacuum test tubes, in addition to being expensive to purchase, must be inserted correctly in the holder, i.e. with the eccentric pierceable area perfectly aligned with the needle tip inside the holder.

[0016] Holders with the needle bent at two points, i.e. ~~roughly~~ ~~approximately~~ S-shaped with the two end parts parallel and ~~the~~ ~~a~~ slanted intermediate part slanting, are also known.

[0017] The part of the needle inside the holder is generally in a central to or coaxial position with respect to the holder, whereas the outer part of the needle is eccentric and out of line. Said holders with needle bent at two points are described in ~~the patent~~ US Patent 3520292.

[0018] The production of said holders with needle bent at two points requires the pre-bending of the needle, the creation around its slanting slanted part of the circular wall which ~~constitutes~~ provides the bottom of the holder and, lastly, the creation of the cylindrical wall of the holder.

[0019] All said work phases involve lengthy production times, the need to position and align the various parts, the possibility of inaccuracy and imperfect joining of the various parts. Consequently, the production of said holders with a bent needle is very costly.

[0020] Further, ~~said~~ Said holders with a bent needle are not convenient for use, ~~also among others~~ due to the fact that ~~in practice~~ their production process does not ~~allow~~ provide for the outer part of the needle to be ~~positioned in correspondence with the~~ coordinated with the outer edge of the casing.

[0021] ~~Said~~ The distance of the needle from the edge of the casing, albeit shorter than the distance existing in the holders with a central needle, limits the insertion of ability to insert the needle into the vein and all the sampling operations.

#### BRIEF SUMMARY OF THE INVENTION

[0022] In order to eliminate the above-mentioned disadvantages, a new process has been designed for the production of holders with a needle bent at two points and which can be used with interchangeable vacuum test tubes for taking blood samples.

[0023] ~~The aim~~An objective of the new process is to produce a holder with a needle bent at two points ~~in~~with only a few simple ~~stages~~steps.

[0024] A further ~~aim~~objective of the new process is to produce a holder with a needle bent at two points and having the outer part of the needle ~~practically~~essentially aligned with the outer edge of the casing, that is, with a much narrower or nil penetration angle.

[0025] A further ~~aim~~objective of the new process is to produce a holder with a needle bent at two points ~~without the possibility of inaccuracy~~without inaccuracies, imperfections, non alignments or incorrect orientation.

[0026] ~~The aim~~A further objective of the new holder with a needle bent at two points is to facilitate the insertion of the ~~holder~~ needle into the vein without causing the patient discomfort or pain.

[0027] A further ~~aim~~objective of the new holder is to facilitate the insertion of the holder needle into the vein with no need for the nurse to check the position of the tip of the needle.

[0028] A further ~~aim~~objective of the new holder is to facilitate the insertion of the holder needle into the vein with no need for the nurse to raise the patient's skin.

[0029] A further ~~aim~~objective of the new holder is to facilitate the insertion of the holder needle into the vein, avoiding the risk of perforating the vein from side to side.

[0030] A further ~~aim~~objective of the new holder is to permit the use of common vacuum test tubes provided with seal cap suitable for central perforation.

[0031] These and other ~~direct and complementary aims~~advantages are achieved through the implementation of the new process for the production of holders with a needle bent at two points, which holders can be used with interchangeable vacuum test tubes for taking blood samples, and through the product obtained therefrom.

[0032] The new holder, which is preferably of the disposable type, comprises a generically substantially cylindrical casing closed at one end, designed to receive vacuum test tubes with a

seal cap adapted for a central perforation, and a shaped needle, preferably consisting of two parallel straight sections not lying on the same axis, joined by a further slanting slanted or generically S-shaped section, said. Said needle being is joined to the casing so that its portion inside the casing is coaxial with said casing, and so that its portion outside the casing and facing the same is shaped and, in its end part, parallel and eccentric to the axis of the casing, while an outer support wall or front connection wall of the casing acts as a thrust bearing for bearer against the needle.

[0033] The casing features a wall designed to house and join the angled, bent or shaped section of the needle to the casing.

[0034] The holder also has the additional advantage of being disposable, thus avoiding all possible health risks for the users.

[0035] The process for the production of the new holder with needle bent at two points includes the complete production of the casing with a connection wall, the insertion of the needle still straight and with the angled ends correctly oriented into the end circular wall of the casing, the fixing affixing of said needle to said circular end wall, the double bending of the needle until it adheres to the slanting slanted connection wall and is aligned with the outer edge of the casing, and the final fixing affixing of the needle to at the end of the slanting slanted connection wall.

[0036] Said connection wall or outer support wall can also be used as a grip for the new holder.

#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0037] The characteristics of the new process for the production of the new holder with needle bent at two points and of the product obtained therefrom will be better illustrated by the following description, with reference to the attached drawings attached as a non-restrictive example.

[0038] Figure 1 shows an axonometric a perspective view of a first embodiment the new holder, the holder comprising a casing (C) and a shaped needle (A).

[0039] Figure 2 shows a side cross section of said the holder of Fig. 1.

[0040] Figure 3 shows a side cross-section of a second embodiment of the new holder.

## DETAILED DESCRIPTION OF THE INVENTION

[0041] Turning first to Figs. 1-2, there is shown a first embodiment of the invention. The A shaped needle (A) consists of three consecutive sections (A1, A2, A3), of which the two extreme sections (A1, A3) are parallel and not lying on the same axis. The intermediate section (A2) connects said two extreme sections (A1, A3) and is slanting slanted with respect to each of them.

[0042] Both of said extreme sections (A1, A3) have an angled or slanting slanted tip (A11, A31), in order to permit facilitate the penetration into the skin and into a vein at one end and the perforation of, and penetration into, the seal cap of a vacuum test tube, respectively at the other end.

[0043] The casing (C) consists of a cylinder (C1) closed on the front side (C2) and provided with outer tabs (C3) at the other end.

[0044] On the front closing wall (C2) of the casing (C) the shaped needle (A) is applied, so that an end section (A3) of said needle (A) is positioned inside the casing (C), coaxial with the cylindrical part (C1) of the casing (C).

[0045] The other end (A1) of the shaped needle (A) is positioned outside the casing (C) and is substantially aligned with the lower outer cylindrical surface of the casing (C).

[0046] Due to the position of the shaped needle (A) with respect to the casing (C), its intermediate section (A2) is positioned outside the casing (C) and facing the front closing wall (C2) of the casing (C).

[0047] The tip (A11) of the needle (A) that is outside the casing (C) has the angled, or slanting side (A11)(A11) facing upwards or facing the entre center or the axis of the casing(C).

[0048] The casing (C) features a connection wall (C4) designed to house and connect the intermediate section (A2) of the needle (A) with the casing (C).

[0049] The lower edge of said connection wall (C4) is parallel to the ~~last lower~~ outer section (A1) of the needle (A) and provides a sliding surface for the holder (C) during the introduction of the needle (A).

[0050] The contact surface between said connection wall (C4) and the needle (A), in particular the intermediate ~~slanting~~ slanted section (A2) of the needle (A), is ~~generically~~ typically semicircular, preferably with a slight undercut, in order to correctly house and retain the needle (A).

[0051] This connection or support wall (C4) can also be used as a grip for the new holder.

[0052] Two caps (T1, T2) are provided, which can be applied to protect and cover the end sections (A1) and (A3)(A1, A3) and the two tips (A11, A31) of the needle (A).

[0053] The casing (C), or part of it, can ~~bear the colour~~ be imprinted with the color of the needle gauge international code.

[0054] Figure 3 shows ~~in section~~ a possible ~~the side cross-section of a~~ variant of the invention, in which the needle (A) is bent in two parts (Ala, A3a), ~~of which~~ more particularly, an end part (A3a) ~~of the needle (A)~~ is included inside the casing (C) and is coaxial with it, while the ~~other~~ and a second end part (Ala) ~~of the needle (A)~~ is positioned outside the casing (C) and slanting slanted with respect to said casing (C).

[0055] The process for the production of said new holder with a needle bent at two points comprises only a few simple ~~stages~~steps.

[0056] Initially the ~~whole~~ casing (C) is produced, preferably by ~~moulding~~ of molding a thermoplastic material, inclusive of ~~with~~ the outer tabs (C3) and ~~with the~~ slanting the slanted connection wall (C4). ~~The~~ A hole for housing the needle (A) is provided on the front wall (C2).

[0057] The needle (A), linear and not yet bent, is inserted in said hole ~~of~~ in said front wall (C2) of the casing, in such a way ~~as so~~ to correctly position its end section (A3) inside the casing (C).

[0058] In this insertion phase, the needle (A) is already positioned with the ~~slanting tip~~ (A11) slanted tip (A11) correctly arranged positioned, in particular more particularly, facing upwards with respect to the connection wall (C4).

[0059] At this point the needle (A) is fixed affixed to the front wall (C2) of the casing (C), for example by means of glue with an adhesive.

[0060] Subsequently the needle (A) is bent twice: the first operation bends initially the needle (A) is bent so that it adheres to is in contact with the connection wall (C4), and in particular, positioning it more particularly, it is positioned in the semicircular housing of said wall (C4), the second; a successive bending operation, at the end of the connection wall (C4), aligns the end section (A1) of the needle (A) with the outer surface of the casing (C) at the end of connection wall (C4) and with the sliding slanted surface of the connection wall (C4).

[0061] Lastly, the two sections (A1, A2) of the needle (A) outside of the casing (C) are fixed affixed to the connection wall (C4), preferably by means of glue an adhesive, in correspondence with the end of the connection wall (C4) opposite the casing (C).

[0062] The method described above for the production of the new holder with a needle bent at two points requires the simple moulding molding of the casing (C) and the preparation of the needle (A) in straight form and with an angled tip (AII)(A11), the insertion of the needle (A) into the casing (C) and, lastly, the bending and joining of the needle (A) to the casing (C) and to the connection wall (C4).

[0063] The new holder constituted and produced as described above offers considerable advantages.

[0064] After removing the cap (T1) from the needle (A), the nurse grips the new holder by its cylindrical body (C1) or the wall or connection wall (C4), leaving the outer section (A1) of the needle (A) facing downwards upwards.

[0065] Consequently, the new holder in the nurse's hand is already in the correct position for use, with the tip (AII)(A11) of the needle (A) already correctly facing upwards with respect to the patient's skin and vein.

[0066] The eccentric position of the needle (A1) with respect to the casing (C), and in particular its position aligned with the outer surface of the casing (C), allows the nurse to insert the needle (A) into the skin and vein with a minimum penetration angle.

[0067] The new holder, with its greatly reduced or nil penetration angle, significantly reduces the discomfort or pain caused to the patient and avoids possible vein perforation errors.

[0068] The new holder, with its greatly reduced penetration angle, facilitates the insertion of the needle (A) into the vein.

[0069] The new holder with the eccentric needle (A) allows the nurse to correctly insert the needle (A) into the vein with no need to take any particular precautions, such as raising the patient's skin or varying the penetration angle during penetration.

[0070] The reduced penetration angle of the new holder considerably reduces the risk of perforating the vein from side to side.

[0071] The new holder, having the needle section (A3) inside the casing (C) positioned coaxially with the casing ~~itself~~, permits the use of the common and widespread vacuum test tubes with seal cap ~~for~~designed for a central perforation.

[0072] Therefore, with reference to the preceding description and the attached drawings, the following claims are put forth.